संगणक सांकेतांक - 202006241529268713

राज्यामध्ये कोविड -१९ उपाययोजनेतंर्गत कोविड - १९ चाचण्यांचे बळकटीकरण करणेबाबत

महाराष्ट्र शासन
वैद्यकीय शिक्षण व औषधी द्रव्ये विभाग,
शासन परिपत्रक क्रमांक :संकीर्ण-२०२०/प्र.क्र. २७ / औषधे-२
गोकुळदास तेजपाल रुग्णालय आवार, नविन इमारत, ९ वा मजला,
लोकमान्य टिळक मार्ग, मुंबई - ४०० ००१.
दिनांक : २३ जून , २०२०.

वाचा :-

१. आयसीएमआर संस्थेद्वारे Advisory to start rapid antibody based blood test for COVID-19बाबत दिनांक ०४ एप्रिल २०२० रोजी दिलेल्या मार्गदर्शक सूचना
२. सचिव, आरोग्य व कुटुंब कल्याण मंत्रालय, भारत सरकार, नवी दिल्ली याचे पत्र क्रमांक VIP /4/2020/ECD-1 (Vol-J),dated 17.04.2020
३. सचिव, आरोग्य व कुटुंब कल्याण मंत्रालय,भारत सरकार ,नवी दिल्ली यांचे अर्ध शासकीय पत्र क्रमांक ECD/COVID -19/Misc/2020,dated 19.06.2020

सध्या सर्वत्र पसरलेलया कोविड -१९ संसर्गजन्य आजाराच्या अनुषंगाने विविध उपयायोजना केल्या जात आहेत. कोविड रुग्णांच्या चाचणी करिता अचूकता व एकाचवेळी चार ते पाच तासांच्या कालावधीत ९० नमूने (Sample)तपासणीची क्षमता असणारी Real Time RTPCR या चाचणी प्रणालीस सुवर्ण मानाकिंत दर्जा प्राप्त आहे.सदर चाचणीसाठी वैशिष्टपूर्ण व सुसज्जता व जैवीक सुरक्षा व सुविधांची आवश्यकता असते.

TrueNat आणि CBNAATया चाचणी प्रणालीचा क्षयरोग व अन्य संसर्गजन्य आजारांचे निदान करण्यासाठी जिल्हा तसेच प्राथमिक आरोग्य केंद्र स्तरावर यशस्वीपणे वापर सदर चाचणी प्रणालीचा विशिष्ट (Customized ) स्वरूपाचे कार्टेज वापरून कोविड -१९ चाचण्या केल्या जातात. राज्यामध्ये आजमितीसभारतीय आयुर्विज्ञान अनुसंधान परिषद (आयसीएमआर) संस्थेने मान्यता प्रदान केलेल्या सुमारे १०४, Real Time RTPCR,TrueNat आणि CBNAAT शासकीय व खाजगी कोविड चाचणी प्रयोगशाळा कार्यरत आहेत. तथापी असे असूनही कोविड चाचण्याची क्षमता व त्याचे बळकटीकरण करण्याची नितांत आवश्यकता आहे.याबाबत मलेरिया, लिशमिनीया, तसेच अन्य विषाणू व जिवाणूजन्य श्वसन आजारांच्या शीघ्र निदानामध्ये (early diagnosis)Rapid Antigen based तत्वावर आधारित चाचणी प्रणालीचा वापर करण्यात येतो. सदर धर्तीवर आयसीएमआर संस्था कोविड -१९ तपासणी त्वरीत ,पर्यायी व विश्वसनीय पर्यायाच्या शोधात होती.

त्यानुषंगाने याबाबत उपरोक्त दिनांक १९.०६.२०२० च्या पत्रान्वयेभारतीय आयुर्विज्ञान अनुसंधान परिषद(आयसीएमआर) संस्थेने खालीलप्रमाणे सूनचा दिलेल्या आहेत.

१. एसडी बायोसेन्सर या उत्पादकांनी त्यांच्या मनेसर गुरूग्राम येथील उत्पादन युनिटमध्ये SARS - COV-२ या साथरोगाच्या जलद निदान चाचणीकरता Antigen based प्रणालीवर आधारित चाचणीकरीता उत्पादित केलेल्या Standard Q COVID-19 Ag Kitचे आयसीएमआर व एम्स,नवी दिल्ली या संस्थांनी स्वतत्रपणे मुल्यमापन केले आहे. त्यामध्ये सदर निदान प्रणाली Very high specificity with moderate sensitivity असलयाचे आढळून आले आहे. आयसीएमआर संस्थेने सदर कीटचा प्रतिबंधित क्षेत्र (कन्टेनमेन्ट झोन ) व रुग्णालयांमध्ये कोविड निदानाकरिता सुवर्ण मानांकन प्राप्त आरटीपीसीआर प्रणालीसह सदर कीटचा वापर करण्याची शिफारस केलेली आहे. याबाबत आयसीएम संस्थेने दिनांक १४.०६.२०२० अन्वये मार्गदर्शक सूचना निर्गमित केल्याआहेत. सदर पत्र सोबत जोडले आहे. **(परिशिष्ट -१ )** म्हणून जोडले आहे. सदर मार्गदर्शक सूचना खालील संकेतस्थळावर उपलब्ध आहे. https://www.icmr.gov.in/pdf/covid/strategy/Advisory_for_rapid_antigen_test१४०६२०२०.pdf सदर प्रणाली कोणत्या घटकांकरिता वापरण्यात यावी याबाबतच्या स्पष्ट शिफारशी आयसीएमआर संस्थेद्वारे तयार करण्यात आले आहे. **(परिशिष्ट -२ )**

२. आयसीएमआर संस्थेने प्रमाणित केलेल्या Standard Q COVID-19 Ag Kit उपलब्धतेबाबतची माहिती आयसीएमआर संस्थेच्या उपरोक्त दिनांक १९.०६.२०२० **(परिशिष्ट -३ )** च्या पत्रात नमूद आहे.

३. आयसीएमआर संस्थेने उपरोक्त कीट संबधी तांत्रिक सहाय्य करिता खालील प्रमाणे अधिकाऱ्याची नियुक्ती केली आहे.

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| डॉ.सिध्दार्थ गिरी, वैज्ञानिक ई आयसीएमआर |
| भ्रमणध्वनी क्रमांक - +९१८७५४६१७८९२ |
| ईमेल - Email: sidhartha.g@icmr.gov.in |

४. RTPCR, TrueNat आणि CBNAATया चाचण्यांच्या माहिती बरोबर ॲटीजन डिटेक्शन तत्वारील चाचण्यांची माहितीसुध्दा प्रचलित आयसीएमआर डेटा एन्ट्री पोर्टलवरील स्वतंत्र रकान्यात भरण्यात यावी याची कृपया सर्वसंबधितांनी नोंद घ्यावी.

५. सचिव, आरोग्य संशोधन विभाग व महासंचालक यांच्या दिनांक ०३.०६.२०२० (परिशिष्ट -४ ) पत्राच्या अनुषंगाने आयसीएमआर संस्थेने राज्यास कोविड शोध मोहिमेत आघाडीवर कार्यरत असलेल्या लक्षणेविरहित (asymptomatic) आरोग्य सेवक,स्वच्छता सेवक, सुरक्षासेवक इत्यादींमध्ये कोविडची लक्षणे आहेत किंवा कसे यांची तपासणी करण्यासाठी IgG antibody assays चा वापराबाबत मागदर्शक सूचना दिलेल्या आहेत. आरसीएमआर संस्थेने ELISA आणि CLIA kits च्या वापराबाबतच्या मागदर्शक सूचनांची यादी https://www.icmr.gov.in/pdf/covid/kits/ELISA_CLIA_Kits_List_०३०६२०२०.pdf या संकेतस्थळावर उपलब्ध आहे. आयसीएमआर संस्थेच्या उपरोक्त दिनांक १९.०६.२०२० च्या पत्रान्वये Antibody चाचणीच्या सर्व निकालाची माहिति mmurhekar@gmail.comया ई मेलवर पाठविणेबाबतचे सूचित केलेले आहे.

६. चाचणी,पाठपुरावा व उपचार (Test, Track and Treat ) या कार्यपध्दतीद्वारेच कोविड -१९ संसर्गजन्य आजाराचा प्रतिबंध करणे व मानवी जीव वाचविणे हा एकमेव पर्याय आहे. यास्तवराज्यातील प्रत्येक भागातील कोविड -१९ आजाराची लक्षणे असणाऱ्या प्रत्येक व्यक्तीस कोविड -१९ चाचणी करण्यासाठी व्यापक प्रमाणात सुविधा उपलब्ध करून देणे गरजेचे आहे. तसेच संसर्गाचा प्रतिबंध करण्यासाठी संपर्क शोध यंत्रणाचे अधिक बळकटीकरण करणे आवश्यक आहे. सदर बाबीच्या अनुषंगाने कोणत्याही चाचणी प्रणालीद्वारे कोविड चाचणी करण्याऱ्या प्रत्येक व्यक्तीची त्यास भारत सरकाने उपलब्ध करून दिलेल्या कोणत्याही ओळखपत्राद्वारे पडताळणी करणे आवश्यक आहे. याबाबत कोविड चाचणी करण्यात येणाऱ्या व्यक्तींनी दिलेले भ्रमणध्वनी क्रमांक चुकीचे असल्याचे निदर्शनास आलेले आहे. सबब सदर चाचणी करण्यास येणाऱ्या व्यक्तीने उपलब्ध करून दिलेल्या भ्रमणध्वनी क्रमांकाची पडताळणी सदर क्रमांकावर Miss Call देवून करणे शक्य आहे. त्याप्रमाणे आवश्यकतेनुसार पडताळणीची कार्यवाही करावी.

७. उपरोक्त वाचा येथे नमूद दिनांक ०४.०४.२०२० (परिशिष्ट - ५)च्या मागदर्शक सूचनानुसार तसेच आरोग्य आणि कुटुंब कल्याण मंत्रालय, नवी दिल्ली यांच्या दिनांक १७.०४.२०२० (परिशिष्ट - ६ ) नुसार Rapid Antibody चाचणी करणेबाबतच्या मार्गदर्शक सूचना देण्यात आलेल्या आहेत.त्याचप्रमाणे आयसीएमआर संस्थेने प्रमाणित केलेल्या Antibody Test Kitची यादी दिनांक ०३.०६.२०२० आणि १९.०६.२०२० (परिशिष्ट -७ ) अन्वये प्रसिध्द केलेली आहे. सदर बाबी आयसीएमआर संस्थेच्या खालील संकेतस्थळावर उपलब्ध आहेत

१. https://www.icmr.gov.in/pdf/covid/kits/ELISA_CLIA_Kits_List_०३०६२०२०.pdf
२. https://www.icmr.gov.in/pdf/covid/kits/Antibody_based_tests_१९०६२०२०.pdf

८. महाराष्ट्र राज्यातील सर्व शासकीय / निमशासकीय /खाजगी / महानगरपालिका / नगर परिषद / धर्मदाय / खाजगी रुग्णालये तसेच प्रयोगशाळा यांना आयसीएमआर संस्थेने कोविड -१९ चाचणीकरिता Antigen TEST आणि Antibody Test याबाबत निर्देशीत केलेल्या मार्गदर्शक सूचनेनुसार सदर Antigen Test आणि Antibody Test चा व्यापक प्रमाणावर वापर करण्यास प्रोत्साहित करण्यात येत आहे. यानुसार त्यांनी त्यांच्याकडे दाखल होणाऱ्या रुग्णांवर आवश्यकतेनुसार सदर चाचण्या कराव्यात आणि या चाचण्यांची माहिती आयसीएमआर संस्थेच्या संकेतस्थळावरील विहीत प्रपत्रात नियमीत भरावी. सदर चाचण्यांची माहिती सार्वजनिक आरोग्य विभाग (परिशिष्ट-८) (ssumaharashtra@gmail.com ) जिल्हाधिकारी / महानगरपालिका / नगर परिषद व इतर संबंधित अधिकृत संस्थांना वेळोवेळी निर्देशित केल्यानुसार नियमीतपणे सादर करण्याबाबत कार्यवाही करावी.

९. सेट्रल ड्रग्ज स्टॅंडर्ड कंट्रोल ऑर्गनायझेशन ( CDSCO ) यांनी दिनांक १७.०६.२०२० अन्वये कोविड -१९ च्या "Rapid/CLIA/ELISA kits approved for testing of COVID -१९ with the condition" त्यांच्या संकेतस्थळावर प्रसिध्द केलेली आहे. (परिशिष्ट -९ )

भारतीय आयुर्विज्ञान अनुसंधान परिषद ( आयसीएमआर ) व सेट्रल ड्रग्ज स्टॅंडर्ड कंट्रोल ऑर्गनायझेशन ( CDSCO ) या संस्थांनी दिलेल्या वरील सूचना तसेच याबाबत वेळोवेळी देण्यात येणाऱ्या अद्यावत सूचना / निर्देश इत्यादीच्या अनुषंगाने राज्यातील सर्व शासकीय / खाजगी रुग्णालये आणि शासकीय व खाजगी प्रयोगशाळा यांनी व्यापक प्रमाण प्रमाण कोविड -१९ चाचण्या करण्याबाबत कार्यवाही करावी.

महाराष्ट्राचे राज्यपाल यांच्या आदेशानुसार व नावाने.

सहपत्र : परिशिष्ट १ ते ९.

( डॉ. संजय मुखर्जी )
सचिव, महाराष्ट्र शासन

प्रति,

१. मा. मुख्यमंत्री महोदयांचे प्रधान सचिव, मुख्यमंत्री सचिवालय, मुंबई
२. मा. उपमुख्यमंत्री महोदयांचे सचिव, मंत्रालय, मुंबई
३. मा.मंत्री (वैद्यकीय शिक्षण ) यांचे खाजगी सचिव
४. मा. मंत्री ( आरोग्य ) यांचे खाजगी सचिव, मंत्रालय, मुंबई
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६. मा. राज्यमंत्री (आरोग्य ) मंत्रालय, मुंबई
७. मा. मुख्य सचिव, महाराष्ट्र राज्य,मुंबई
८. प्रधान सचिव , सार्वजनिक आरोग्य विभाग, मंत्रालय, मुंबई
९. प्रधान सचिव , नगर विकास विभाग, मंत्रालय, मुंबई
१०.प्रधान सचिव , करोना नियंत्रण कक्ष , मंत्रालय , मुंबई
११. आयुक्त, मुंबई महानगरपालिका, मुंबई

१२.आयुक्त , अन्न व औषधे प्रशासन, मुंबई
१३. धर्मदाय आयुक्त,महाराष्ट्र राज्य, मुंबई
१४. सर्व विभागीय आयुक्त
१५. सर्व जिल्हाधिकारी
१६. सर्व आयुक्त महानगरपालिका
१७. व्यवस्थापकीय संचालक, हाफकीन जीव औषध निर्माण महामंडळ, मुंबई
१८ संचालक, वैद्यकीय शिक्षण आणि संशोधन, मुंबई
१९ संचालक आरोग्य सेवा संचालनालय, मुंबई
२० सर्व अधिष्ठाता, शासकीय वैद्यकीय महाविद्यालय व रुग्णालय, मुंबई
२१ सर्व मुख्याधिकारी,नगर परिषद,
२२ सर्व जिल्हा शल्य चिकीत्सक
२३.निवडनस्ती (औषधे-२)

परिपत्रका सोबतच्या परिशिष्टांची सविस्तर माहिती.

| परिशिष्ट क्र. | विषय | वेब लिंक |
|---|---|---|
| परिशिष्ट-१ | ICMR Advisory on Use of Rapid Antigen Detection Test for COVID-१९ दिनांक १४.०६.२०२०. | https://www.icmr.gov.in/pdf/covid/strategy/Advisory_for_rapid_antigen_test१४०६२०२०.pdf |
| परिशिष्ट - २ | ICMR यांचे दिनांक १९.०६.२०२० च्या पत्रामधील प्रपत्र-१ Key points to remember for use of COVID-१९ quick antigen detection assay | ---- |
| परिशिष्ट - ३ | सचिव, आरोग्य व कुटुंब कल्याण मंत्रालय,भारत सरकार ,नवी दिल्ली यांचे अर्ध शासकीय पत्र क्रमांक ECD/COVID -१९/Misc/२०२०,dated १९.०६.२०२० | ---- |
| परिशिष्ट - ४ | सचिव, आरोग्य संशोधन विभाग व महासंचालक यांचे दिनांक ०३.०६.२०२० चे पत्र. | https://www.icmr.gov.in/pdf/covid/kits/ELISA_CLIA_Kits_List_०३०६२०२०.pdf |
| परिशिष्ट - ५ | आयसीएमआर संस्थेद्वारे Advisory to start rapid antibody based blood test for COVID-१९ बाबत दिनांक ०४.०४.२०२० रोजी दिलेल्या मार्गदर्शक सूचना | https://www.icmr.gov.in/pdf/covid/strategy/Advisory_Antibody_Testing_०४०४२०२०.pdf |
| परिशिष्ट - ६ | आरोग्य आणि कुटुंब कल्याण मंत्रालय, नवी दिल्ली यांच्या दिनांक १७.०४.२०२० नुसार Rapid Antibody चाचणी करणेबाबतच्या मार्गदर्शक सूचना | https://www.icmr.gov.in/pdf/covid/strategy/Rapid_Antibody_test_Protocol.pdf |
| परिशिष्ट - ७ | Guidance on rapid antibody kits for COVID-१९ दिनांक १९.०६.२०२० | https://www.icmr.gov.in/pdf/covid/kits/Antibody_based_tests_१९० ६२०२०.pdf |
| परिशिष्ट - ८ | सार्वजनिक आरोग्य विभाग यांचे माहिती भरावयाचा नमूना. | ---- |
| परिशिष्ट -९ | Central Drugs Standard Control Organization : Rapid/CLIA/ELISA kits approved for testing of COVID -१९ with the condition दिनांक १७.०६.२०२०. | https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTk५Mw== |

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परिशिष्ट - १




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**भारतीय आयुर्विज्ञान अनुसंधान परिषद**
**स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार**

**Indian Council of Medical Research**
**Department of Health Research, Ministry of Health and Family Welfare, Government of India**

# Advisory on Use of Rapid Antigen Detection Test for COVID-19

**Dated: 14th June 2020**

## Background:

1. Real time RT-PCR is the gold standard frontline test for diagnosis of COVID19. Various open and closed RT-PCR platforms (Open systems RT-PCR machines, TrueNat and CBNAAT) are currently being used for COVID19 diagnosis in India. All these platforms require specialized laboratory facilities in-terms of equipment, biosafety & biosecurity. Minimum time taken for the test varies between different systems with a minimum of 2-5 hours including the time taken for sample transportation. These specifications limit the widespread use of the RT-PCR test and also impedes quick augmentation of testing capacity in various containment zones and hospital settings.

2. In view of this, there is urgent need of a reliable point-of-care rapid antigen detection test with good sensitivity and specificity for early detection of the disease.

3. There are no reliable antigen detection tests available worldwide, which could be used as rapid point of care tests for quick detection of COVID-19 positive patients. Such tests would help in proper implementation of the Govt. strategy to test, track and treat. Such tests will also help in allaying the anxiety and fear of healthcare workers and aid in better clinical management of the patients. In view of this, an independent two site evaluation of the only available or stand-alone antigen detection assay available in India, **Standard Q COVID-19 Ag detection kit,** was conducted with an aim to evaluate its sensitivity, specificity and feasibility of use as a point-of-care test for early detection of SARS-CoV-2.

4. **Brief description of the Standard Q COVID-19 Ag detection:**

   i) **Standard Q COVID-19 Ag detection kit** is a rapid chromatographic immunoassay for qualitative detection of specific antigens to SARS-CoV-2. has been developed by SD Biosensor, a South Korea based company, having its manufacturing unit in Manesar, Gurugram, India.
   ii) Each test kit comes with an inbuilt COVID antigen test device, viral extraction tube with viral lysis buffer and sterile swab for sample collection.
   iii) One Nasopharyngeal swab needs to be collected using the customized sample collection swab provided with the kit. No other sample (throat swab, bronchoalveolar lavage or sputum) should be used.
   iv) After sample collection, the swab should be immersed and squeezed in the viral extraction buffer, provided with the kit. This buffer inactivates the virus thereby reducing biosafety and




biosecurity requirements. The test does not work if the sample is collected in the usual Viral Transport Media (VTM), routinely used for collection of OP/NP swabs.

v) Once the sample is collected in the extraction buffer, it is stable only for one hour. Therefore, the antigen test needs to be conducted at the site of sample collection in the healthcare setting. Transportation to the lab is not recommended.

vi) Once the sample goes into the buffer and is mixed properly, the buffer tube cap needs to be replaced with a nozzle provided with the kit and 2-3 drops of the sample with buffer are put into the well of the test strip.

vii) The test can be interpreted as positive or negative after 15 minutes of putting the sample into the well by appearance of test and control lines, which can be read with a naked eye, requiring no specialized equipment. **Maximum duration for interpreting a positive or negative test is 30 minutes.** After that the test strip should be discarded.

viii) The test kit should be stored between 2° to 30° C.

ix) Detailed instructions for use can be accessed through the video link: https://youtu.be/mBdaOHJWxl4

## 5. Validation of the Test:

**I. Sites:**

Standard Q COVID-19 Ag detection assay by SD Biosensor was evaluated independently by the following agencies:

i) Indian Council of Medical Research, Delhi; and

ii) All India Institute of Medical Sciences, Delhi

**II. Results:**

i) Standard Q COVID-19 Ag rapid antigen detection test has a very high specificity (i.e. ability to detect true negatives). Specificity ranged from 99.3 to 100% at the two sites.

ii) Sensitivity of the test (i.e. ability to detect true positives) ranged from 50.6% to 84% in two independent evaluations, depending upon the viral load of the patient. Higher viral load correlated with higher sensitivity.

## 6. Conclusions and Recommendations:

i) Standard Q COVID-19 Ag detection assay by SD Biosensor is the standalone antigen detection test which is available in India and has been validated.

ii) ICMR encourages other manufacturers / developers who have antigen detection assays to come forward for validation.

**iii) <u>In view of its high specificity while relatively low sensitivity, ICMR recommends the use of Standard Q COVID-19 Ag detection assay as a point of care diagnostic assay for testing in the following settings in combination with the gold standard RT-PCR test:</u>**

**A. Containment zones or hotspots** *(to be performed onsite under strict medical supervision and maintaining kit temperature between 2° to 30° C.):*

i) All symptomatic Influenza Like Illness (ILI).

ii) Asymptomatic direct and high-risk contacts with co-morbidities (*lung disease, heart disease, liver disease, kidney disease, diabetes, neurological disorders, blood disorders*) of a confirmed case to be tested once between day 5 and day 10 of coming into contact.

**B. Healthcare settings** *(to be performed onsite under strict medical supervision and maintaining kit temperature between 2° to 30° C):*

i) All symptomatic ILI patients presenting in a healthcare setting and are suspected of having COVID19 infection.

ii) Asymptomatic patients who are hospitalized or seeking hospitalization, in the following high-risk groups:

- Patients undergoing chemotherapy
- Immunosuppressed patients including those who are HIV+;
- Patients diagnosed with malignant disease;
- Transplant patients;
- Elderly patients (>65 yrs of age) with co-morbidities (lung disease, heart disease, liver disease, kidney disease, diabetes, neurological disorders, blood disorders)

iii) Asymptomatic patients undergoing aerosol generating surgical / non-surgical interventions:

- Elective/emergency surgical procedures like neurosurgery, ENT surgery, dental procedures;
- Non-surgical interventions like bronchoscopy, upper GI endoscopy and dialysis;

***ILI case is defined as one with acute respiratory infection with fever ≥ 38°C AND cough.***

**Use of the rapid antigen test is recommended in A & B categories above subject to the following conditions:**

*i)* ***Suspected individuals who test negative for COVID-19 by rapid antigen test should be definitely tested sequentially by RT-PCR to rule out infection, whereas a positive test should be considered as a true positive and does not need reconfirmation by RT-PCR test.***

*ii) Samples (only nasopharyngeal swabs) to be collected by a trained healthcare worker following full infection control practices including use of proper PPE.*

*iii) The test should be conducted* ***on-site*** *under strict medical supervision and within one hour of sample collection in extraction buffer.*

*iv)* **ALL TESTING RESULTS USING THE STANDARD Q COVID-19 AG DETECTION ASSAY MUST ESSENTIALLY BE ENTERED ON THE ICMR COVID-19 PORTAL AND ALSO COMMUNICATED TO THE STATE AUTHORITIES AND OFFICIALS OF THE INTEGRATED DISEASE SURVEILLANCE PROGRAMME (IDSP) ON A REAL-TIME BASIS.**

परिशिष्ट - 2

**Annexure 1:**

**Key points to remember for use of COVID-19 quick antigen detection assay:**

- Minimum time taken for RT-PCR test is 2-5 hours.
- Antigen detection test cis a rapid point of care test and has no specialized laboratory requirements.
- One nasopharyngeal swab is to be collected and tested **onsite within one hour of sample collection.**
- Sample collection and testing is to be performed by a trained health care worker with proper PPE.
- Can be interpreted between 15 to 30 minutes with a naked eye.
- Kit needs to be stored between 2° to 30° C.

**Rapid antigen detection test for COVID 19 can be used to test individuals in the following categories:**

A. **Containment zones or hotspots**:

i) All symptomatic Influenza Like Illness (ILI).

ii) Asymptomatic direct and high-risk contacts (with co-morbidities) of a lab confirmed case.

B. **Healthcare settings**:

i) All symptomatic ILI patients presenting in a healthcare setting and are suspected of having COVID19 infection.

ii) Asymptomatic patients in high risk groups: undergoing chemotherapy; immunosuppressed patients; patients suffering with malignant disease; transplant patients; elderly patients (>65 yrs of age) with co-morbidities

iii) Asymptomatic patients undergoing aerosol generating surgical / non-surgical interventions like elective/emergency surgical procedures: Neurosurgery, ENT surgery, dental procedures; and non-surgical interventions like bronchoscopy, upper GI endoscopy and dialysis;

**Interpretation of the test:**

**Symptomatic Individuals who test negative by the antigen test should be definitely tested sequentially by RT-PCR to rule out COVID19 infection,** whereas a positive test should be considered as a true positive and does not need reconfirmation by RT-PCR test.

परिशिष्ट - ३



सत्यमेव जयते




प्रोफेसर (डा.) बलराम भार्गव, पदम श्री

एमडी, डीएम, एफआरसीपी (जी.), एफआरसीपी (ई.), एफएसीसी, एफएएचए, एफएएमएस, एफएनएएस, एफएएससी, एफ.एन.ए., डी.एस.सी.

सचिव, भारत सरकार

स्वास्थ्य अनुसंधान विभाग

स्वास्थ्य एवं परिवार कल्याण मंत्रालय एवं

महानिदेशक, आई सी एम आर

**Prof. (Dr.) Balram Bhargava,** Padma Shri

MD, DM, FRCP (Glasg.), FRCP (Edin.), FACC, FAHA, FAMS, FNASc, FASc, FNA, DSc

**Secretary to the Government of India**

Department of Health Research

Ministry of Health & Family Welfare &

**Director-General, ICMR**

भारतीय आयुर्विज्ञान अनुसंधान परिषद

स्वास्थ्य अनुसंधान विभाग

स्वास्थ्य एवं परिवार कल्याण मंत्रालय

भारत सरकार

वी. रामलिंगस्वामी भवन, अंसारी नगर

नई दिल्ली - 110 029

**Indian Council of Medical Research**

Department of Health Research

Ministry of Health & Family Welfare

Government of India

V. Ramalingaswami Bhawan, Ansari Nagar

New Delhi - 110 029


**DO.No.ECD/COVID19/Misc./2020**
**Dated 19th June 2020**

**Subject: Ramping up testing for COVID-19 in containment zones and hospitals.**

**Dear (Chief Secretaries of all states)**

1. Real Time RT-PCR is the gold standard test for detecting cases of COVID-19. The test requires specialized laboratory setup with specific biosafety and biosecurity precautions to be followed. Average time taken is around 4-5 hours from receipt of sample to getting the result. The advantage of this platform lies in its accuracy of detection as well as ability to run upto 90 samples in a single run. However, in view of the specialized laboratory requirements, this test cannot be performed at every district level labs which do not have molecular virology facilities.

2. The TrueNat and CBNAAT systems have also been deployed for diagnosis of COVID-19 in view of availability of customized cartridges for COVID-19 diagnosis. These platforms have widespread availability even at district and PHC as these platforms are widely used for diagnosis of Tuberculosis as well as other infectious diseases. These platforms have a quick turnaround time (30 -60 minutes) but only 1-4 samples can be tested in one run, limiting the maximum numbers that can be tested to 24-48 samples / day. The viral lysis buffer that comes with the COVID-19 cartridges inactivates the virus and poses minimum biosafety hazard. Safety is further augmented by the closed nature of these platforms and minimum sample handling. These features have facilitated use of these platforms at grass root level thereby increasing access to testing.

3. In an effort to ramp up the testing capacity, ICMR has approved a total of 960 labs in public and private sector. However, inspite of these developments in testing, there is an urgent need to introduce rapid point of care diagnostic tests to make testing widely available in all parts of the country.

4. Rapid antigen-based detection assays have been used successfully for early diagnosis of diseases like Malaria, Leishmania, viral and bacterial respiratory infections etc. Such tests can be used as point of care diagnostics in field settings and have minimal biosafety and biosecurity requirements. In view of this, ICMR had been exploring alternate quick and reliable options for diagnosis of COVID-19.


Tele.: 26588204, 26589620, Fax (Off.) : 91-11-26588662, E-mail: secy-dg@icmr.gov.in

5. ICMR and AIIMS, Delhi independently evaluated the stand-alone rapid point of care antigen detection assay for quick diagnosis of SARS-CoV-2 developed by SD Biosensor with manufacturing unit at Manesar, Gurugram. The assay is known as **Standard Q COVID-19 Ag kit**. On validation, the test has been found to have a very high specificity with moderate sensitivity. ICMR now also recommends use of Standard Q COVID-19 Ag detection test as a point of care diagnostic assay for testing in the containment zones as well as hospitals in combination with the gold standard RT-PCR test. ICMR has issued an advisory dated 14th June 2020. In this regard, which may be accessed at: https://www.icmr.gov.in/pdf/covid/strategy/Advisory_for_rapid_antigen_test_14062020.pdf. The advisory clearly delineates the recommended groups of individuals who should be tested using the antigen detection assay. Key points in the advisory are enclosed as Annexure 1 for your perusal.

6. **Standard Q COVID-19 Ag kit** is available with the local vendor of SD Biosensor. Contact details are as follows:

   **Dr. CS Bedi**
   Mobile No: +919810426069
   Email: drbedi@icloud.com

   ICMR has negotiated the price of the kit. The upper price cap negotiated by the Committee is Rs. 450/-.

   For any technical assistance /clarifications, details of the ICMR contact point are given below:

   Dr. Sidhartha Giri, Scientist E, ICMR
   Mobile No: +918754617892
   Email: sidhartha.g@icmr.gov.in

7. **Kindly note that in addition to the details of all the tests conducted by the RT-PCR, TrueNat, CBNAAT, results of Antigen detection assay also need to be entered into the existing ICMR data entry portal where a separate field has been incorporated to accommodate all testing data emerging through the rapid antigen test.**

8. In addition, vide earlier letter No. dated from Secy DHR & DG to all states, ICMR has advised states on use of IgG antibody assays for conducting serosurveys in asymptomatic frontline workers like healthcare workers, sanitation workers, security staff etc. for assessing their serostatus for COVID-19. Guidance of ICMR on the list of available ELISA and CLIA kits can be accessed at https://www.icmr.gov.in/pdf/covid/kits/ELISA_CLIA_Kits_List_03062020.pdf. As the apex research organization of the country, ICMR is mandated to review and conduct research on the evolving trends of the disease and accordingly advise the states / country on the public health policies. In view of this, I advise you to share all the antibody testing results with ICMR at the email id given below: mmurhekar@gmail.com.

9. Since test, track and treat is the only way to prevent spread of infection and save lives, it is imperative that testing should be made widely available to all symptomatic individuals in every part of the country and contact tracing mechanisms for containment of infection are further strengthened. Therefore, it is advised that all the patients who are being tested by any of the above methods, may be requested to share one personal Identity, issued by Govt. of India to establish the authenticity of the individual. Also, it has been noted that the phone numbers shared by individuals at the time of testing are often

incorrect. Therefore, it is advisable that at the time of testing, a missed call should be given on the shared phone number to verify its correctness,

10. In view of this, I request you all to kindly take required steps to scale up the testing capacity in your respective state by adopting various available testing options, making testing available to all symptomatic individuals in your state. This will enable early detection and containment of infection which in turn would save several lives.

With regards,

Yours sincerely,

Balram Bhargava

**( Balram Bhargava )**

**Copy to:**

1. Smt. Preeti Sudan, Secretary (HFW), MOHFW, New Delhi
2. Shri Rajesh Bhushan, OSD, MOHFW, New Delhi
3. All Health Secys of States / UTs

Annexure 1:

**Key points to remember for use of COVID-19 quick antigen detection assay:**

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ii) Asymptomatic direct and high-risk contacts (with co-morbidities) of a lab confirmed case.

B. **Healthcare settings**:

i) All symptomatic ILI patients presenting in a healthcare setting and are suspected of having COVID19 infection.

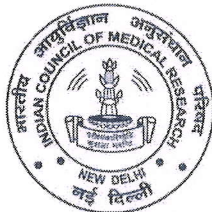
ii) Asymptomatic patients in high risk groups: undergoing chemotherapy; immunosuppressed patients; patients suffering with malignant disease; transplant patients; elderly patients (>65 yrs of age) with co-morbidities

iii) Asymptomatic patients undergoing aerosol generating surgical / non-surgical interventions like elective/emergency surgical procedures: Neurosurgery, ENT surgery, dental procedures; and non-surgical interventions like bronchoscopy, upper GI endoscopy and dialysis;

**Interpretation of the test:**

**Symptomatic Individuals who test negative by the antigen test should be definitely tested sequentially by RT-PCR to rule out COVID19 infection**, whereas a positive test should be considered as a true positive and does not need reconfirmation by RT-PCR test.

परिशिष्ट - ४




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कल्याण मंत्रालय, भारत सरकार

**Indian Council of Medical Research**
**Department of Health Research, Ministry of Health and Family Welfare, Government of India**

**Date:** 03.06.2020

# LIST OF IgG ELISA KITS FOR COVID 19 VALIDATED BY ICMR IDENTIFIED VALIDATION CENTRES

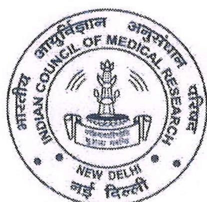
| Sl. No | Name of Company | Name of the Kit | *Batch Number |
|---|---|---|---|
| 1. | Zydus Cadila Healthcare Ltd., Ahmedabad, Gujarat, India | COVID Kavach ELISA IgG | CoV2HI GG96-001<br>CoV2HI GG96-002<br>CoV2HI GG96-003 |
| 2. | Euroimmun US Inc., USA | Euroimmun Anti- SARS-COV-2 ELISA IgG | E200420AW |
| 3. | Calbiotech Inc., USA | Erbalisa COVID-19 IgG ELISA | CVG6087 |

The **IgG ELISA** and **CLIA** tests are recommended only for the following purpose:

i. Serosurveys to understand the proportion of population exposed to infection including asymptomatic individuals. Depending upon the level of seroprevalence of infection, matching public health interventions can be implemented for prevention and control of the disease.
ii. Survey in high risk or vulnerable populations (health care workers, frontline workers, immunocompromised individuals, individuals in containment zones etc) to know who has been infected in the past and has now recovered.

**Please Note:**

- The ELISA tests have been validated in the laboratory. However, the performance of the test may be subject to variation under field conditions.
- *Above listed ELISA tests are validated with the mentioned batch number only. Responsibility for batch to batch consistency lies with the manufacturer.
- **IgG ELISA / CLIA tests which are US-FDA approved** can be used directly after due marketing approval from DCGI.
- Names and contact details of the manufacturers of COVID Kavach IgG ELISA is enclosed for reference.




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**ICMR has transferred COVID Kavach ELISA IgG technology to below mentioned pharma companies:**

| S.No. | Name of Company | Contact Details |
|---|---|---|
| 1 | **Zydus Cadila Healthcare Ltd** | Mr Vivek Kant Tripathi<br>Zydus Corporate Park, 4th Floor, B Wing,<br>Scheme No. 63, Survey No. 536,<br>Near Vaishnodevi Circle, Sarkhej-Gandhinagar Highway,<br>Ahmedabad-382481, Gujarat, India<br>Mobile: +919717273066<br>Email:vivekkant.tripathi@zyduscadila.com |
| 2 | **Meril Diagnostics Pvt. Ltd** | Mr Paparaidu Sanapala<br>Dy. General Manager(Technical Head)<br>Vapi, Gujarat, India<br>Mobile: +919574144456<br>Email: paparaidu.sanapala@merillife.com |
| 3 | **Voxtur Bio Ltd.** | Dr Veeraal Gandhi<br>Chairman<br>Plot No. A-1, Royal Compound, Tamanman Kaman<br>Bhivandi Road, Vasai, Palghar,<br>Mumbai-401208, India<br>Mobile: +91-9819720123<br>Email: veeraal@voxturbio.com |
| 4 | **Trivitron Healthcare Pvt. Ltd** | Mr Nitin Sawant,<br>President<br>D -134, MIDC, Industrial Area, Shirvane,<br>Opposite Dr. D YPatil University, Nerul,<br>Navi Mumbai – 400706, India<br>Mobile: +91 8291282827<br>Email: santosh.jagtap@trivitron.com |
| 5 | **J. Mitra & Co. Pvt Ltd** | Ms Sangeeta Gupta<br>Head Technical<br>A-180, Okhla Industrial Area, Phase-1,<br>New Delhi - 110020, India<br>Mobile:+918800192205<br>Email : tcmgr@jmitra.co.in |
| 6 | **Karwa Enterprises Pvt Ltd** | Dr. Vivek Varma, Head – Operations<br>Rapid Diagnostic Group of Companies<br>B-82, Industrial Area, G.T. Karnal Road,<br>New Delhi – 110033, India<br>Mobile: +91 9535998155<br>Email: drjindal@rdgc.in |
| 7 | **Avecon Healthcare Pvt Ltd** | Mr Rajesh Aggarwal<br>Plot No. 338, Industrial Growth Centre<br>Saha, Haryana- 133104, India<br>Mobile: + 91 9315445391<br>Email : exportzone@aveconhealthcare.com |

परिशिष्ट - ५

**INDIAN COUNCIL OF MEDICAL RESEARCH**

**DEPARTMENT OF HEALTH RESEARCH**

# Advisory to start rapid antibody based blood test for COVID-19 (4 April 2020)

**Strategy for areas reporting clusters (containment zone) and in large migration gatherings/evacuees centres**

***Cases of Influenza Like Illness (ILI) to be monitored in health facilities. Any surge in cases to be monitored and brought to the notice of Surveillance Officer/CMO for additional investigation.***

As a matter of abundant precautions, all symptomatic ILI persons should be advised home quarantine for 14 days.

At facility level, symptomatic ILI individuals to be tested using rapid antibody tests.

- **Antibody test negative:**
  - If warranted, confirm by real-time RT-PCR using throat/nasal swab.
    - RT-PCR negative: Likely non-COVID-19 ILI
    - RT-PCR positive: ***Confirmed COVID-19 Case*** and action as per protocol to be initiated for isolation, treatment and contact tracing.

    OR
  - If real-time RT-PCR not done, home quarantine and repeat antibody testing after 10 days of the last rapid antibody test.
    - Antibody test negative: Likely non-COVID-19 ILI.
    - Antibody test positive: there is possibility of recent infection, quarantine for another 10 days.

- **Antibody test positive**: After clinical assessment, treatment in hospital or isolation as per protocol. Action as per protocol to be initiated for contact tracing.

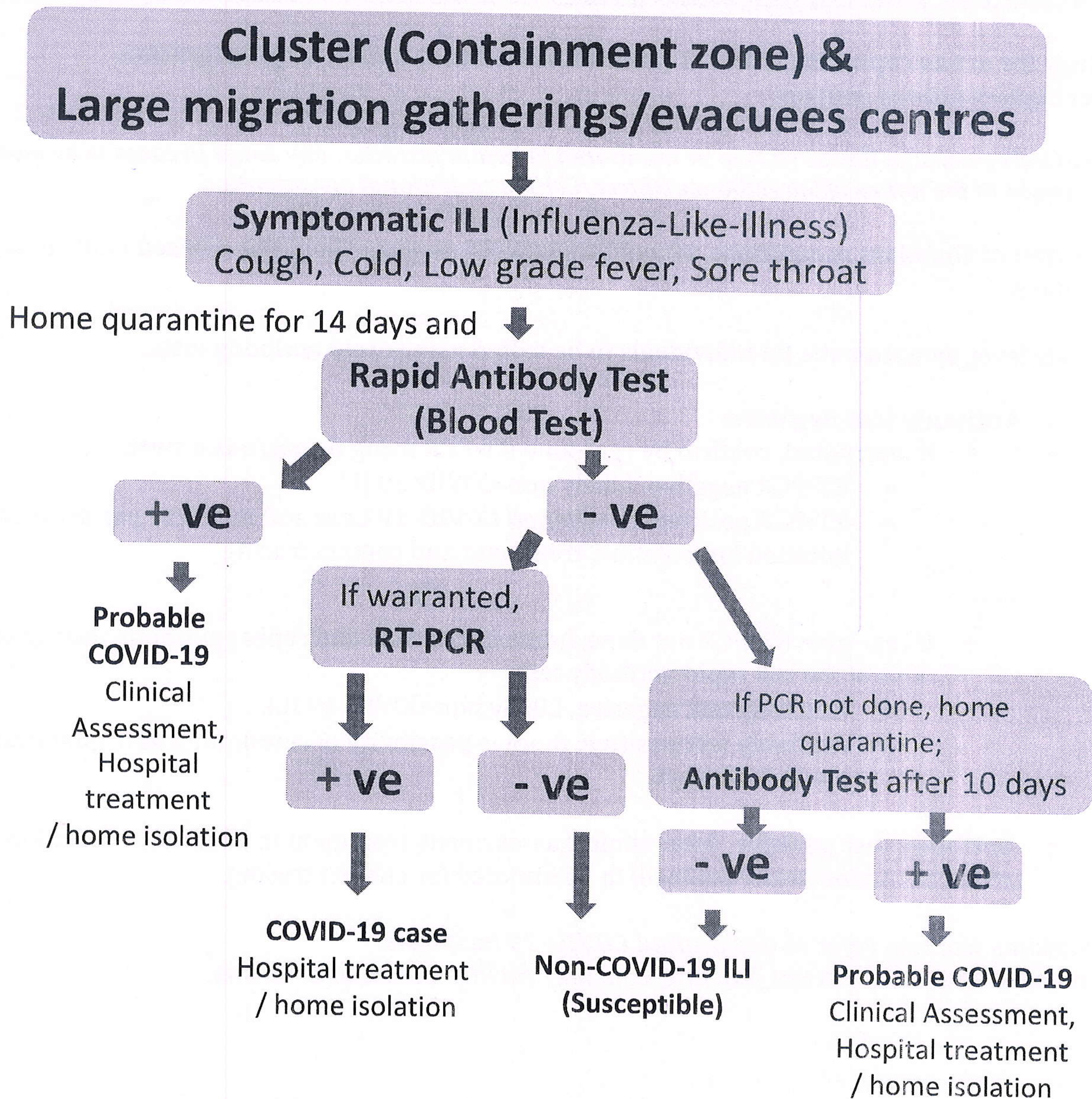
***If symptoms worsen, refer to designated COVID-19 hospitals.***
***When home quarantine is not feasible, consider facility-based quarantine.***

**General Guidelines:**

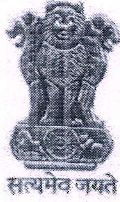
- Healthcare workers doing the rapid antibody test to use gloves, mask, and head covers.
- Healthcare workers collecting throat/nasal swab to follow standard national infection control guidelines.
- The rapid antibody tests approved by US-FDA/CE-IVD or non-CE-IVD validated by ICMR-NIV with marketing approval by DCGI be used.
- In order to ensure that all such cases are monitored and necessary action is initiated with respect to infectious disease management, details of all test results shall be uploaded in ICMR portal.
- All such organizations are duty bound to register themselves to ICMR portal and upload the data in real-time.
- Failure to do so, they will be held liable to action under Disaster Management Act, 2005.

# STRATEGY FOR USE OF RAPID ANTIBODY BASED BLOOD TEST

(4 April, 2020)



पशिशिष्ट - ६



सत्यमेव जयते




प्रोफेसर (डा.) बलराम भार्गव, पदम श्री
एमडी, डीएम, एफआरसीपी (जी.), एफआरसीपी (ई.), एफएसीसी,
एफएएचए, एफएएमएस, एफएनएएस, एफएएससी, एफ.एन.ए., डी.एस.सी.
सचिव, भारत सरकार
स्वास्थ्य अनुसंधान विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय एवं
महानिदेशक, आई सी एम आर

**Prof. (Dr.) Balram Bhargava,** Padma Shri
MD, DM, FRCP (Glasg.), FRCP (Edin.),
FACC, FAHA, FAMS, FNASc, FASc, FNA, DSc
**Secretary to the Government of India**
Department of Health Research
Ministry of Health & Family Welfare &
**Director-General, ICMR**

भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
भारत सरकार
वी. रामलिंगस्वामी भवन, अंसारी नगर
नई दिल्ली - 110 029

**Indian Council of Medical Research**
Department of Health Research
Ministry of Health & Family Welfare
Government of India
V. Ramalingaswami Bhawan, Ansari Nagar
New Delhi - 110 029

**D.O.No. VIR/4/2020/ECD-I (Vol.I)**
Dated: 17th April 2020

**Addl.Chief Secretaery/Secretary/Principal Secretary Health (All States)**

Sub: **Protocol for using 'Rapid antibody test' in Hot area – epidemiological studies and surveillance**

I am writing to you with reference to the rapid antibody test kits for COVID-19 testing. It is understood that many States intend to use these kits in affected areas.

2. The National Task Force at ICMR has carefully reviewed the data evolving from various countries on use of such kits. Based on available evidence, the testing strategy for COVID-19 has been revised further. The revised document is enclosed for your reference.

3. It is critical to understand the following key facts while using the rapid antibody tests:

- Gold standard frontline test for COVID-19 diagnosis is **real time PCR based molecular test**, which is aimed at early virus detection.
- The rapid antibody test cannot replace the frontline test.
- The rapid Antibody test is a **supplementary tool** to assess the prevalence of the diseases within a specific area / perimeter.
- The rapid antibody test will **only be of utility after a minimum of 7 days of onset of symptoms**.
- Data about these rapid tests is emerging and understanding of their utility for diagnosis is still evolving.
- The rapid tests are useful for **epidemiological studies and surveillance purposes**.
- THE TEST HAS TO BE DONE UNDER STRICT MEDICAL SUPERVISION.

4. The enclosed ICMR advisory is for Hot spots. In case your state does not have a Hot spot, these tests may be used for:-

a) Any hotspot which may emerge in future

OR

b) As a surveillance tool for epidemiological purposes in such areas where cases have not emerged so far.

5. Before starting the rapid test, it should be registered on covid19cc.nic.in/ICMR and data related to the test should be reported on the same.

With best regards

Yours sincerely

Balram Bhargava

( Balram Bhargava)

Enclosed: As above

CC: **Chief Secretary/Administrators**

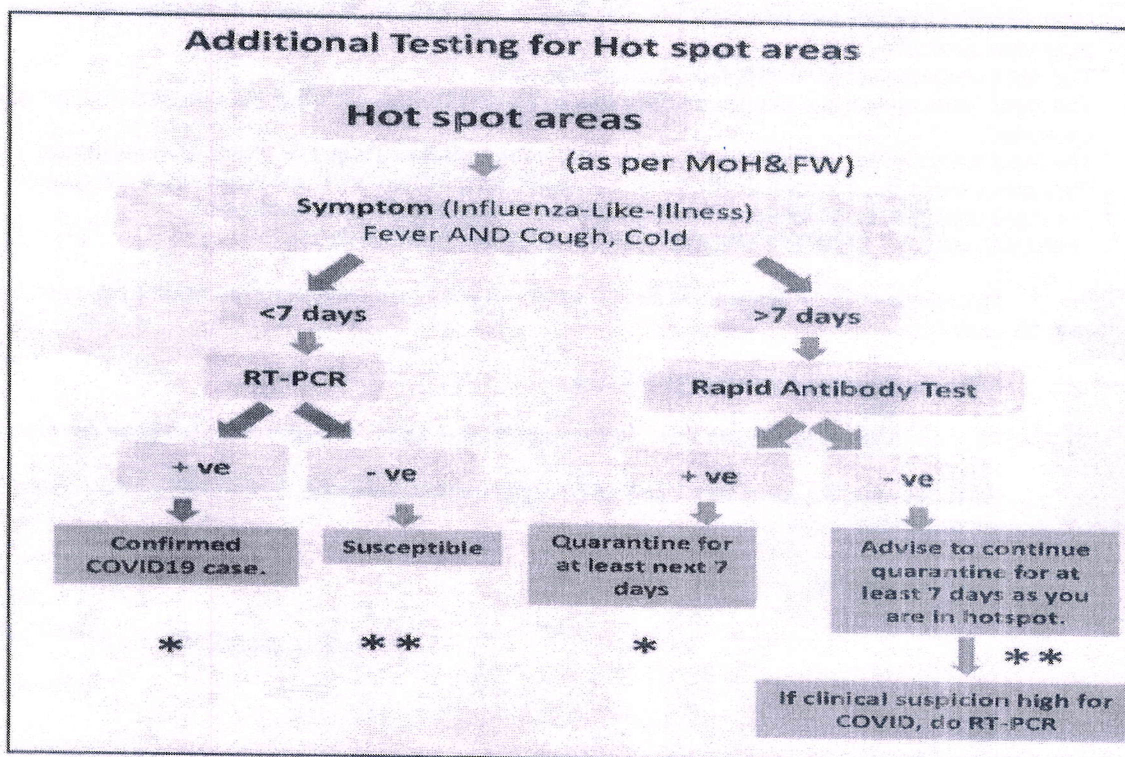
Tele.: 26588204, 26589620, Fax (Off.) : 91-11-26588662, E-mail: secy-dg@icmr.gov.in

## A. COVID-19 Testing Strategy for India (Recommended for the entire country)

**Real-Time PCR (RT-PCR) test and Point-of-Care molecular diagnostic assays are recommended for diagnosis of COVID-19 among individuals belonging to the following categories:**

- All symptomatic individuals who have undertaken international travel in the last 14 days
- All symptomatic contacts of laboratory confirmed cases
- All symptomatic health care workers
- All patients with Severe Acute Respiratory Illness (fever AND cough and/or shortness of breath)
- Asymptomatic direct and high-risk contacts of a confirmed case should be tested once between day 5 and day 14 of coming in his/her contact

## B. Additional (in addition to A) Testing recommended in hot spots




** Refer to Hospital if symptoms appear / worsen*

*** Follow precautions, social distancing, use masks, frequent hand washing, avoid unnecessary travel)*

Baban Bhagat

परिशिष्ट - ७



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स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health and Family Welfare, Government of India

**Date: 19/06/2020**

# Guidance on rapid antibody kits for COVID-19

**Till date, 56 antibody based rapid tests have been validated, and the following were found to be satisfactory. 11 of these kits are manufactured in India.**

| S.No. | Name of Company | Name of Kit | Lot no./Batch no. |
|---|---|---|---|
| 1. | BioMedomics (CE-IVD), China | Biomedomics COVID-19 IgM IgG Rapid Test | 20200226 |
| 2. | Voxtur Bio Ltd, Surat (Gujarat), India | Coronavirus (COVID-19) IgG/IgM Rapid Test | PCCV200301S |
| 3. | VANGUARD Diagnostics, Delhi, India | COVID-19 IgM/IgG Antibody Detection Card Test | RCOVID200301T |
| 4. | HLL Lifecare Limited, Gurugram (Haryana) India | Makesure COVID-19 Rapid test | CVCT030420<br>CVCT0204203<br>CVCT0104202 |
| 5. | Lab Care Diagnostics India Pvt. Ltd, Mumbai (Maharashtra), India | ACCUCARE IgM/IgG Lateral Flow Assay kit | CVC 200401 |
| 6. | NuLifecare, Noida (Uttar Pradesh), India | Abchek COVID-19 IgM/IgG Antibody Rapid Test | NUL/COV-19/R&D/001 |
| 7. | Alpine Biomedicals, Ambala (Haryana), India | One Step Corona Virus (COVID-19) IgM/IgG Antibody Test | A10420<br>A20420 |
| 8. | Medsource Ozone Biomedicals, Haryana, India | COVID 19 IgM/IgG Rapid Test Kit (ver 2.0) | COV-002 |
| 9. | Immuno Science India Pvt. Ltd, Pune (Maharashtra), India | Immuno Quick Rapid Test for Detection of Novel Coronavirus (COVID-19) IgM/IgG Antibodies | E142001 |
| 10 | SD Biosensors, Healthcare Pvt. Ltd., Gugugram (Haryana), India | Standard Q Covid -19 IgM/IgG Duo test – One Step Rapid Antibody test | E054002<br>E054004 |
| 11. | BMT Diagnostics (Rafael Diagnostic), Israel | BMT COVID-19 IgG/IgM Rapid Test Kit | COV20030059<br>COV20030059-1 |
| 12. | SIDAK Life Care Pvt. Ltd., New Delhi, India | One Step COVID-19 IgM/IgG Antibody | COVID19S004A<br>COVID19S004B<br>COVID19S004C |
| 13. | Diagnocure, Solan (Himachal Pradesh), India | Xamin COVID-19 Rapid Test Device | DI/COV19/R&D/001<br>DI/COV19/R&D/002 |

**Rapid antibody tests are not recommended for diagnosis of COVID-19 infection**

- Can be done on blood/serum/plasma samples
- Test result is available within 30 minutes
- Test may come positive after 7-10 days of infection
- The test may remain positive for several weeks after infection
- Positive test indicates exposure to SARS-CoV-2
- Negative test does not rule out COVID-19 infection

- **These rapid antibody test kits have been validated in the laboratory. However, the performance of the kits may be subject to variation under field conditions.**
- **Above listed kits are validated with the mentioned batch number only. Responsibility for batch to batch consistency lies with the manufacturer.**



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Date: 19/06/2020

## Guidance on rapid antibody kits for COVID-19

| S. No. | Kit Detail | Lot no./Batch no. |
|---|---|---|
| 14. | SARS-CoV-2 Antibody test (Lateral flow method): Guangzhou Wondfo Biotech<br>Mylan Laboratories Limited (CE-IVD)<br>M R Roofs Private Ltd<br>Abbott Laboratories<br>Zydus Cadilla | #<br>W19500309<br>W19500302<br>W19500351<br>W19500338 |
| 15. | COVID-19 IgM/IgG Antibody Rapid Test: ZHUHAI LIVZON DIAGNOSTICS (CE-IVD) | # CK2003010410 |

**# The marketing licenses to the distributors of these 2 companies have been cancelled by the Central Drugs Standard Control Organization (CDSCO).**

Antibody based rapid tests which are US-FDA approved can be used directly after due marketing approval from DCGI.

परिशिष्ट - ८

## 8 A LABWISE REPORT

GOVERNMENT

DATE:

| SR. NO. | GOVERNMENT LABS | TESTS CAPACITY | NUMBER OF KITS AVAILABLE | TOTAL SAMPLES COLLECTED | | TOTAL NUMBER OF POSITIVES | | TOTAL NUMBER OF NEGATIVES | | TOTAL NUMBER OF RESULTS AWAITED | REMARKS |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | TODAY | PROGRESSIVE | TODAY | PROGRESSIVE | TODAY | PROGRESSIVE | TODAY | |
| | | | | | | | | | | | |

## 8 A LABWISE REPORT

PRIVATE

| SR. NO. | PRIVATE LABS | TESTS CAPACITY | NUMBER OF KITS AVAILABLE | TOTAL SAMPLES COLLECTED | | TOTAL NUMBER OF POSITIVES | | TOTAL NUMBER OF NEGATIVES | | TOTAL NUMBER OF RESULTS AWAITED | REMARKS |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | TODAY | PROGRESSIVE | TODAY | PROGRESSIVE | TODAY | PROGRESSIVE | TODAY | |
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परिशिष्ट - e

**Rapid / CLIA/ ELISA Kits approved for testing of Covid-19 with the conditions.**

**Date: 17.06.2020**

| S. No. | Name of the Firm | Type of Kit | Country |
|---|---|---|---|
| 1 | M/s CPC Diag. Pvt. Ltd, Chennai | Chemiluminscent Immuno Assay IgG & IgM (CLIA)<br><br>CE Approved and in Australia | M/s Shenzhen YHLO Biotech Co. Ltd. China |
| 2 | M/s Eris LifeSciences, Ahmedabad | Florescent, IgG & IgM | M/s Maccure Biotechnology .Ltd. China<br><br>CE Approved and in China |
| 3 | M/s Cadila Healthcare Ltd, Ahmedabad | Antibody rapid test IgG/IgM | M/s. Hangzhou Clongene Biotech Co.Ltd. China<br><br>CE Approved |
| 4 | M/S Vishat Diagnostics Pvt Ltd Mumbai | Antibody rapid test IgG/IgM | M/S Hangzhou All Test Biotech co Ltd China<br><br>CE approved |
| 5 | S.D. Biosensor Delhi | Fluorescent Rapid ANTIGEN Test | M/s S.D. Biosensor, korea<br><br>CE Approved |
| 6 | M/S Trivitron Healthcare Pvt Ltd ,Chennai | Antibody test IgG/IgM CE approved | M/s Autobio Diag Co Ltd, China |
| 7 | M/S Trivitron Healthcare Pvt Ltd ,Chennai | Chemiluminescence Immuno Assay CLIA CE approved | M/s Shenzhen New Industries Biomedical Engineering (SNIBE), China |
| 8 | M/S SNIBE Diagnostics (India), Gurgaon | Chemiluminescence Immuno Assay CLIA CE approved | M/s Shenzhen New Industries Biomedical Engineering (SNIBE), China |

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| 9 | M/S Vishat Diagnostics Pvt Ltd Mumbai | ELISA CE approved | M/S Zhenghou Human well Biocel Technology Ltd China |
| 10 | M/s Sowar Private Ltd Delhi | Rapid Antibody test IgG/IgM CE approved | M/S Getein Biotech Inc China |
| 11 | M/S Immunoshop India Pvt Ltd Thane | Chemiluminescence Immuno Assay CLIA CE approved | M/s Shenzhen New Industries Biomedical Engineering (SNIBE), China |
| 12 | M/S Athenese Dx Pvt Ltd Chennai | Rapid Antibody test IgG/IgM CE approved | M/s Beijing Genese Biotech Inc , China |
| 13 | M/S Bioline Diagnostics , Delhi | Antibody test IgG/IgM CE approved | M/S Hangzhou All Test Biotech co Ltd China CE approved |
| 14 | M/S Immunoshop India Pvt Ltd Thane | Antibody test IgG/IgM CE approved | M/s Goldsite Diagnostics Inc, China |
| 15 | Accurex Biomedical Pvt Ltd, Thane | Antibody test IgG/IgM CE approved | M/S Getein Biotech Inc, China |
| 16 | Indelox Global Distribution, Pvt Ltd, Bangalore | Antibody test IgG/IgM CE approved | M/S Dongguan Bosh Biotechnology China |
| 17 | M/S POCT Services Pvt Ltd Delhi | Antibody test IgG/IgM CE approved | M/S Zybo Inc China |
| 18 | M/S Krishgen Biosystems Mumbai | Antibody test IgG/IgM CE approved | M/sWuhan UNScience Biotechnology co Ltd, China |
| 19 | M/s Rapid Diagnostics Pvt Ltd Delhi | Antibody test IgG/IgM CE approved | M/s Hangzhou Biotech Co Ltd China |
| 20 | M/s PTS Diagnostics India Pvt. Ltd. | Antibody test IgG/IgM CE approved | M/s Changsha Sinocare Inc China |
| 21 | M/s Gland Pharma | Antibody test IgG/IgM CE approved | M/S Shanghai Fosun Long March, China |
| 22 | M/s Accrediated Consultant Pvt Ltd | Antibody test IgG/IgM CE approved | M/S Hangzhou All Test Biotech co Ltd China |
| 23 | M/s Accrediated Consultant Pvt Ltd | Antibody test IgG/IgM CE approved | M/S Humasis Co Ltd Korea |
| 24 | M/s Cosmic Scientific Chennai | Antibody test IgG/IgM CE approved | M/S Getein Biotech Inc, China |
| 25 | M/S Agappe Diagnostics Ltd | Antibody test IgG/IgM CE approved | M/s Hangzhou Biotech Co Ltd China |

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| 26 | M/S Trivitron Healthcare Ltd | Antibody test IgG/IgM CE approved | M/S Beijing Lepu Medical Technology Co Ltd China |
| 27 | M/S Rafael Diagnostics, Pune | Antibody test IgG/IgM CE approved | M/S BMT Diagnostics Israel |
| 28 | M/S Matrix Lab Chennai | CLIA CE Approved | Auto-biodiagnostics Co Ltd China |
| 29 | M/S Providence International Labs | Antibody test IgG/IgM CE approved | M/S Hangzhou Reality Tech Co Ltd |
| 30 | M/S Voxtur Bio Ltd | Antibody test IgG/IgM | Indigenous |
| 31 | M/S Vanguard Diag Pvt Ltd | Antibody test IgG/IgM | Indigenous |
| 32 | M/S S.D.Biosensor, Pvt Ltd | Antibody test IgG/IgM Duo(Standard Q) | M/s S.D . Biosensor, Inc South Korea |
| 33 | M/S Weldon Biotech(I) Pvt.Ltd. | iChrome FIA( Fluoracence ImmunoAssay) Covid-19 Ab | M/s Boditech Med Inc. Korea |
| 34 | M/s HLL | Antibody test IgG/IgM | Indigenous |
| 35 | M/s Raymed Trading Group Pvt. Ltd. | Antibody test IgG/IgM CE approved | M/S Beijing Lepu Medical Technology Co Ltd China |
| 36 | Hemogenomics Pvt. Ltd. Bangalore | Antibody test IgG/IgM CE approved | M/S PCL Inc. South Korea |
| 37 | M/s Aracion Technology Pvt. Ltd | Antibody test IgG/IgM CE approved | M/S Hecin Scientific Inc. China |
| 38 | M/s CPC Diagnostics Pvt. Ltd. | Anti SAR- COV-2 ELISA IgA/ IgG | M/s Euroimmune AG Germany |
| 39 | M/s Bilcare Ltd. Pune | Antibody test IgG/IgM CE approved | M/S Getein Biotech Inc, China |
| 40 | M/s Bravo Pharmaceuticals Pvt. Ltd. | Antibody test IgG/IgM CE approved | M/s Biosynex S.A France |
| 41 | M/s Harmony LifeSciences Pvt. Ltd. | Antibody test IgG/IgM CE approved | M/s Humasis Co. Ltd. South Korea |
| 42 | M/s Inbios India, New Delhi | Antibody test IgG/IgM CE approved | M/S Getein Biotech Inc, China |
| 43 | M/s Imperial LifeSciences Pvt. Ltd | Antibody test IgG/IgM CE approved | M/s NewScen Coast Biopharmaceutical Co. Ltd. China |

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| 44 | M/s POCT Services Pvt. Ltd. | Antibody test IgG/IgM CE approved | M/s Gen Body Inc. South Korea |
| 45 | M/s Trivitron Healthcare Pvt. Ltd. | Antibody test IgG/IgM CE approved | M/s Innovita(Tang Shen) Biological Technology Co. Ltd. China |
| 46 | M/s Concept HealthCare | Antibody test IgG/IgM CE approved | M/s Celtex Biotech(Suzhou) Co. Ltd. China |
| 47 | M/s Bio Innovations Thane | Antibody test IgG/IgM CE approved | M/s Primer Design Ltd. U.K |
| 48 | M/s AR KAY Medicos Pvt. Ltd. | Antibody test IgG/IgM CE approved | M/s Humasis Co. Ltd. South Korea |
| 49 | M/s Kin Diagnostics West Bengal | FIA iChroma IgG/IgM CE approved | M/s Boditech Med Inc. South Korea |
| 50 | M/S Aracion Technology Pvt LTd | Antibody test IgG/IgM CE approved | M/s Innovita(Tang Shen) Biological Technology Co. Ltd.China |
| 51 | M/S Meridian Medicare LTD | Antibody test IgG/IgM CE approved | M/s Gen Body Inc. South Korea |
| 52 | M/S SD Bio Sensor Healthcare Pvt Ltd | Standard Q COVID-19 IgG/IgM Duo | Indigenous |
| 53 | M/S Tara Medicos Pvt Ltd Jaipur | Antibody test IgG/IgM CE approved | M/S CELLEX INC,CHINA |
| 54 | M/s Med Source Ozone Biomedicals Pvt Ltd | COVID-19 IgG/IgM Rapid Test | Indigenous |
| 55 | Immunoscience India Pvt Ltd | COVID-19 IgG/IgM Rapid Test | Indigenous |

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| 56 | M/s S.D Biosensor Healthcare Pvt. Ltd. | Standard Q Covid-19 IgG/IgM Combo | M/s S.D Biosensor Inc. Korea |
| 57 | M/s BioHouse Solutions Pvt. Ltd. Delhi | COVID-19 IgG/IgM Rapid Test | M/s Bio Medomics Inc. USA |
| 58 | M/s True Healthcare India Pvt. Ltd. | Antibody test IgG/IgM CE approved | M/s Humasis Co. Ltd. South Korea |
| 59 | M/s Immunoshop India Pvt. Ltd. | Antibody test IgG/IgM CE approved | M/S Shenzhen Cifotrunic Technology Ltd. China |
| 60 | M/s Clini Experts Services Pvt. Ltd. | Antibody test IgG/IgM CE approved | M/s Biocan Diagnostics Inc. Canada |
| 61 | M/s Inbios India, Delhi | Antibody test IgG/IgM CE approved | M/S CELLEX Biotech (Suzhou) Co. Ltd ,CHINA |
| 62 | M/S Synergy Scientific Services Pvt Ltd | Antibody test IgG/IgM CE approved | M/S Schenzhen Reagent Technology Co Ltd China |
| 63 | M/S Bioscience Sales Corp. Delhi | Antibody test IgG/IgM CE approved | M/S Shenzhan Watmind Medical Co. Ltd , China |
| 64 | M/s Gastro Lab India Pvt Ltd | Antibody test IgG/IgM CE approved | M/S Sche Bo Biotech AG, Germany |
| 65 | M/S Doctor Analytical Laboratories Pvt Ltd | Antibody test IgG/IgM CE approved | M/s Biocan Diagnostics Inc. Canada |
| 66 | M/S MDAAC International Pvt Ltd | Antibody test IgG/IgM CE approved | M/S Atlab Link(Beijing) Technology Co Ltd , China |
| 67 | M/S Kin Diagnostics | Antibody test IgG/IgM CE approved | M/S Sugentech Inc South Korea |
| 68 | M/s Alere Medical Pvt. Ltd. | PanBio Antibody test IgG/IgM CE approved | M/s Abbott Rapid Diagnostics Germany Having Mfg. Site at Abon Biopharma(Hangzhou) Co. Ltd. China |
| 69 | M/s Incarp Instruments Pvt. Ltd. Hyderabad | FIA IgG/IgM AntiBody Test CE approved | M/s Boditech Med Inc. South Korea |

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| 70 | M/s Nucleus 18 Turnkey Projects Pvt. Ltd. Telangana | Antibody test IgG/IgM Australian EUA | M/s Innovita (Tangshan) Biological Technology Co. Ltd. China |
| 71 | M/S Elder Projects Ltd Mumbai | Antibody test IgG/IgM CE approved | M/S Shanghai Outdo Biotech Co Ltd China |
| 72 | M/S KDH Biomedicals Pvt Ltd Mumbai | Antibody test IgG/IgM CE approved | M/s Dynamiker Biotechnology (Tianjin) Co Ltd China |
| 73 | M/S KDH Biomedicals Pvt Ltd Mumbai | ELISA IgG and ELISA IgM/IgA CE approved | M/s Dynamiker Biotechnology (Tianjin) Co Ltd China |
| 74 | Bio Dx Healthcare New Delhi | Antibody test IgG/IgM CE approved | M/S Zybio Inc, China |
| 75 | M/s Trivitron Healthcare Pvt LTD | Antibody test IgG/IgM CE approved | M/s Shenzhen Lifotronic Technology Co. Ltd. China |
| 76 | M/s Saffron Naturele Product Pvt. Ltd. U.P | Antibody test IgG/IgM CE approved | M/s Hangzhou Clongene Biotech Co. Ltd. China |
| 77 | M/s Bioplus Healthcare Pvt Ltd Bangalore | Antibody test IgG/IgM CE approved | M/s Cellex BioTech (Suzhou) Co. Ltd. China |
| 78 | M/s N.W Overseas, Haryana | Antibody test IgG/IgM CE approved | M/s Beijing Lepu Medical Technology Co. Ltd. China |
| 79 | M/s Premier Nutraceuticals Pvt. Ltd. | Antibody test IgG/IgM CE approved | M/s Shanghai Outdo Bio Tech Co. Ltd. China |
| 80 | M/s Genetix BioTech Asia Ltd.. | Antibody test IgG/IgM | M/s Sugentech Inc. South Korea |
| 81 | M/S Alpine Biomedicals Pvt Ltd Haryana | Rapid Antibody test IgG/IgM | Indigenous |
| 82 | S A Diagnostics Pvt Ltd Mumbai | Antibody test IgG/IgM | M/S Genrui Biotech Inc China |
| 83. | M/s Abbott Healthcare Pvt Ltd | Chemiluminescent Microparticle Immunoassay With Architect System | M/SAbbott Ireland Diag Div. Ireland |
| 84 | M/s Lab Care Diag, India Pvt Ltd | Antibody test IgG/IgM | Indigenous |

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| 85 | M/S Nulife, Noida | Antibody test IgG/IgM | Indigenous |
| 86 | M/s Tulip Diagnostics Pvt Ltd Goa | Coviscreen-Rapid Double Antigen test for detection of IgG/IgM/IgA | Indigenous |
| 87 | M/s Roche Diagnostics India Pvt. Ltd. Delhi | ECLIA<br>Elecys Anti SARS COV2 | M/s Roche Diagnostics GmbH, Germany |
| 88 | M/s Sidak LifeCare Pvt. Ltd. | Antibody test IgG/IgM | Indigenous |
| 89 | M/s S.D Biosensor HealthCare Pvt. Ltd. | Standard Q COVID-19 IgG/IgM Combo | Indigenous |
| 90 | M/s Diasorin Healthcare India Pvt. Ltd. | CLIA | M/s Diasorin S.P.A, Itlay |
| 91 | M/s Iris Hightech Pvt. Ltd. Delhi | Antibody test IgG/IgM | M/s Pharmact GmbH, Germany |
| 92 | M/s Mindray Medical India Pvt. Ltd. Mumbai | CLIA | M/s Shenzhen Mindray, China |
| 93 | M/s Ortho Clinical Diagnostics India Pvt. Ltd. | Vitros Immunodiagnostic Total Reagent Pack | M/s Ortho Clinical Diagnostics, USA |
| 94 | M/S DiaSys Diagnostics India Pvt Ltd | Antibody test IgG/IgM | M/S Beijing Lepu Medical Technology Co Ltd China |
| 95 | M/S Jetta Labs | Antibody test IgG/IgM | M/s Hanghzhou Test Sea Biotechnology China |
| 96 | M/s V.S Yarns Pvt. Ltd. Ludhiana | Antibody test IgG/IgM | M/s Accobiotech, Malaysia |
| 97 | M/s CliniExperts Services Pvt. Ltd | Antibody test IgG/IgM | M/s Europlaz Technologies, U.K |
| 98 | M/s Cadila Healthcare Ltd. | ELISA | Indigenous |

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| 99 | M/s Deep Meditech Pvt. Ltd. Delhi | Antibody test IgG/IgM | M/s Autobio Diag Co Ltd, China |
| 100 | M/S McW Healthcare Pvt Ltd | Antibody test IgG/IgM | M/s Technogenetics S.r.l Italy |
| 101 | M/S Omega Dx (Asia) Pvt Ltd | ELISA | M/S Genesis Diagnostics Ltd , UK |
| 102 | M/S Abbott Healthcare Pvt Ltd | CMIA | M/S Abbott Ireland |
| 103 | M/S Ortho Clinical Diag. India Pvt. Ltd | CLIA, IgG qualitative immunodiagnostic assay kit | M/S Ortho clinical Diag. UK |
| 104 | M/S Ortho Clinical Diag. India Pvt. Ltd | VITROS (Immunodiagnostics Assay Kit) including IgG,IgA and IgM | M/S Ortho clinical Diag. UK |
| 105 | M/S Athenese-Dx Pvt. Ltd | Antibody test IgG/IgM | M/S CTK Biotech Inc, USA |
| 106 | M/S Tosoh India Pvt Ltd | ELISA IgA, ELISA IgG, ELISA IgM | M/S NovaTec GmbH, Germany |
| 107 | M/S Biorad Laboratories (India) Pvt Ltd | Platellia SARS-COV2 Total Ab | M/S Biorad , France |
| 108 | M/S Novomed Inc Pvt Ltd | ELISA IgG/IgM | M/S Ga Generic Assay GmbH Germany |
| 109 | M/S Ortho Clinical Diag. India Pvt. Ltd | CLIA , Vitros IgG | M/S Ortho clinical Diag. UK |
| 110 | M/S S D Biosensor Healthcare Pvt Ltd | Standard Q COVID-19Ag | Indigenous |
| 111 | M/S J. Mitra | COVID IgM+IgG+IgA Microlisa | Indigenous |

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इमेल द्वारे

जा. क्र. कोविड उ.यो./कोविड किट/१५६५-२०/११ दि. १६जून, २०२०

प्रति,

मा. सचिव
वैद्यकीय शिक्षण व औषधी द्रव्ये विभाग
मंत्रालय, मुंबई-०१

विषय :- COVID-१९ च्या नैदानिक चाचणी करिता वापरण्यात येणाऱ्या Rapid टेस्ट किट बाबत.

महोदय

विषयांकित प्रकरणी शासनास सादर करण्यात येते कि, औषध नियंत्रक (भारत) यांचेद्वारा कोविड १९ च्या चाचणी करिता मान्यता देण्यात आलेल्या Rapid Antigen Test Kit आणि Antibody Rapid Test kit चे उत्पादन व विक्री करणाऱ्या संस्थांची यादी त्यांचे संकेतस्थळ cdsco.gov.in वर प्रसिद्ध केली आहे. सदर यादी ची प्रत यासोबत जोडली आहे.

भारतीय आयुर्विज्ञान अनुसंधान परिषदेने दि. १४/०६/२०२० रोजी त्यांचे संकेतस्थळावर Rapid Antigen detection test for COVID-१९ च्या वापराबाबत मार्गदर्शक सूचना प्रसिद्ध केल्या आहेत.

वरील सर्व बाबी विचारात घेता, औषध नियंत्रक (भारत) यांनी मान्यता दिलेल्या Rapid antigen kit and Rapid antibody किट चा वापर शासनाच्या अखत्यारितील सर्व यंत्रणा जसे वैद्यकीय शिक्षण विभाग व सार्वजनिक आरोग्य विभाग यांचे अखत्यारीतील रुग्णालये, प्रयोगशाळा, केंद्र शासनाची रुग्णालये, खाजगी रुग्णालये व प्रयोगशाळा इ, भारतीय आयुर्विज्ञान अनुसंधान परिषद (ICMR) ने वेळोवेळी निर्गमित केलेल्या मार्गदर्शिकेनुसार(Advisory Notice) कोविड १९ च्या चाचणी करिता करू शकतात.

तरि आपल्या माहितीस्तव सविनय सादर.

आपला

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